## REMARKS

After entry of the above amendments, claims 1, 2, 4, 5, 7-11, and 13-22 are pending in this application. With the amendment to claim 11 making it depend from claim 1, claim 1 is the only independent claim pending in this application.

Claim 1 has been amended to clarify that it is directed to a fine mist spray rather than a composition for producing such a spray. Claims 1, 11 and 20 have been amended to indicate that the fine mist spray is for direct administration to non-facial skin and that the solution has a pH above about 5 to reduce the likelihood of causing nasal irritation and coughing. The amendments are supported on page 6, line 6, page 7, lines 4-7, and page 11, Example 2.

Page 6 of the specification has been amended to correct an advertent inaccuracy in the disclosure. Allantoin and urea were stated to be active anti-acne ingredients. In this regard, enclosed herewith is the packaging for applicant's salicylic acid body spray in which allantoin and urea are listed as "inactive ingredients". Accordingly, allantion and urea have been deleted on page 6.

Attached hereto is a marked-up version of the changes made to the claims by the current amendments. The marked up version is captioned "**Version with markings to show changes made**".

**Acknowledgement of Interview**

Applicant's attorney thanks the Examiner and her supervisor for the December 23, 2002 telephone interview.

**Discussion of Claim Objections**

The amendments to claims 1 and 11 obviate the objections to claims 21 and 22. Claims 21 and 22 have also been amended to make it clear that they are limited to compositions/articles wherein the sole active anti-acne ingredient in the spray is salicylic acid.

**Discussion of Rejections**

There are two 35 USC § 103 rejections made against the claims.

In making a 35 USC § 103 rejection it is incumbent upon the Examiner to establish a prima facie case of obviousness. To do this, three criteria must be met: (1) the prior art references must teach or suggest all the claim limitations; (2) there must be some motivation in the references themselves or the knowledge of the art to combine the teachings of the references; and (3) there must be a reasonable expectation of success in combining the references.

Applicant contends that the Examiner has failed to make out a prima facie case in the two rejections. In the absence of a prima facie case, applicant cannot be required to present evidence that her invention provides unexpected results over the prior art.

**The Rejection Based on Fitzjarrell, Briggs et al., and Guang Lin et al.**

Do the references teach all of the claim limitations? Applicant's claim 1 is directed to "a fine mist spray" "for administration as such only to non-facial body skin" comprising a solution of salicylic acid wherein "the pH of the solution is above about 5 whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced". In this regard, fine mist sprays, because of their particle size, are susceptible to being inhaled into the nose and throat. In addition, applicant found that at low pH such inhaled salicylic acid is likely to cause nasal irritation and coughing. For these reasons, claim 1 specifies that the spray is for administration as such (i.e., in the form of a fine mist spray) only to non-facial body skin and that its pH is sufficiently high to reduce the likelihood of causing nasal irritation and coughing should it inadvertently be inhaled. Note, that the enclosed packaging for applicant's commercial spray states "Do not spray directly on or near your face".

The primary reference, Fitzjarrell, describes a method for treating acne, particularly acne on the "O or elliptically shaped area of the face that includes the nose and chin "(column 1, lines 38-40 and column 2, lines 8-11) that combines a topical spray of niacinamide with an oral

supplement comprising lysine, selenium, zinc and chromium. While Fitzjarrell says the spray can be generated using "Any suitable spraying device such as conventional pump or aerosol sprayers", nothing is specifically said about fine mist sprays.

In the second paragraph of the background section of this patent, Fitzjarrell states that "Mild acne can be treated with ...topical creams containing salicylic acid." The penultimate sentence of that paragraph goes on to state "These treatments are often unsuccessful and may have significant side effects."

Accordingly, Fitzjarrell fails to describe (1) fine mist sprays of any kind and certainly not of salicylic acid (2) sprays that are administered as such only to non-facial body skin (3) anything about the pH of salicylic acid solutions and (4) anything about reducing nasal irritation or coughing caused by inhalation of fine mist sprays. None of these limitations in applicant's claim 1 is described.

The first secondary reference, Briggs et al. teaches topical anti-acne formulations of salicylic acid which use alcohol/water solvents. This reference teaches that the pH of the formulation is "preferably in the range of 1 to about 7, more preferably about 2 to about 5, especially from 2 to about 4 "(col, lines 40-45). Accordingly, while Briggs et al. teach use of a broad range of pHs, it clearly does not teach the particular pH range of applicant's claim 1 and that such range reduces nasal irritation and coughing. In this regard this reference does not teach sprays and its formulations would not be susceptible to being inhaled.

The third reference, Guang Lin, has a similar teaching to Briggs et al. and adds nothing more to teaching the limitations of applicant's claim 1.

In sum then, none of the references of this rejection teach (1) fine mist spray of salicylic acid (2) that are for administration as such to only non-facial body skin and (3) that have a pH above about 5 which results in reduced incidence of nasal irritation and coughing.

**Is there a motivation to combine the teachings of the references?**

As indicated above, Fitzjarrell expressly states that the acne treatments such as topical salicylic acid creams described in the second paragraph of his background section "are often unsuccessful and may have significant side effects." If anything, this teaching is motivation to not substitute a salicylic acid spray for the niacinamide spray. Moreover, even if this substitution was made, the resulting spray would be for administration to the face, indeed to the area including the nose and mouth. In addition neither of the secondary references suggest spray forms of salicylic acid.

**Is there a likelihood of success?**

As indicated above, Fitzjarrell actually teaches away from using salicylic acid. Also there is nothing of record which indicates that a salicylic acid spray would be a suitable substitute for the niacinamide spray in Fitzjarrell's combination therapy. Furthermore, as taught by applicant, salicylic acid sprays administered to the face can be irritating to the nose and throat. That being the case administration of a salicylic acid spray directly to the face as taught by Fitzjarrell could be "unsuccessful and have significant side-effects" -- just as noted by Fitzjarrell in his background section.

In summary, this rejection fails to meet all three criteria for making out a prima facie case of obviousness.

**The Rejection Based on Fitzjarrell, Briggs and Guang Lin in Further View of Stone and Sciarra**

Fitzjarrell, Briggs and Guang Lin are discussed above.

Do Stone or Sciarra remedy the failure of Fitzjarrell, Briggs and Guang Lin to provide a prima facie case of obviousness? Clearly no.

Stone and Sciarra merely teach the general use of aerosol devices for administering cosmetics. They fail to say anything that could lead one to conclude that fine mist sprays of

salicylic acid should be administered directly only to non-facial body skin and at pHs that reduce the likelihood of causing nasal irritation and coughing, both of which are limitations in applicant's claims. Other than generally suggesting that cosmetics can be administered in aerosol form, they provide no motivation for combining their teachings with those of Fitzjarrell and certainly no motivation that would make up for the lack of motivation to combine the teachings of Fitzjarrell with those of Briggs and Guang Lin that would be requisite to making a prima facie case of obviousness. Further, as discussed above, using a fine mist spray of salicylic acid per Fitzjarrell's' teachings is not likely to be successful.

## CONCLUSION

For the above reasons, the rejections are in error because neither provides a prima facie case of obviousness against the claims of this application. Applicant therefore respectfully asks the Examiner to withdraw the rejections and allow this application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 425802000200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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By: Thomas E Ciotti

Thomas E. Ciotti
Registration No. 21.013

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5702
Facsimile: (650) 494-0792

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

**In the Specification**

Please replace the paragraph starting on page 5, line 25 with the following:

The formulation may optionally contain additional anti-acne ingredients to salicylic acid. Examples of such ingredients are: other keratolytic agents such as benzoyl peroxide and α-hydroxyacids such as retinoic acid or derivatives thereof; other anti-acne retinoids such as adapalene, tazaretene; antimicrobials such as penicillins, cephalosporins, other beta-lactams, aminoglycosides, tetracyclines, erythromycin, clindomycin and other antifungal agents; antiseptics such as triclosan, phenoxyisopropanol, resorcinol, chlorhexidine, povidone, and iodine; anti-irritants such as α-bisabolol, farnesol, chamomile extract and glycyrrhetinic acid; and other common anti-acne compositions such as [urea, allantoin,] glycolic acid, azelaic acid and hydroxyquinolines.

**In the Claims:**

Please cancel claims 3 and 14.

Please replace claims 1, 11 and 20-22 with the following rewritten versions thereof:

1. (Thrice Amended) A fine mist pump spray containing no propellant for administration as such only to non-facial body skin to treat acne or acneform conditions thereon[treating acne or acneform conditions] comprising a solution [of anti-acne ingredient(s), said anti-acne ingredients consisting essentially] of salicylic acid wherein the salicylic acid constitutes from about 0.01% to about 20% by weight of the solution and the pH of the solution is above about 5 whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced.

11. (Thrice Amended) An article of manufacture for producing the fine mist spray of claim 1 comprising a solution [of anti-acne ingredient(s), said anti-acne ingredient(s) consisting essentially] of salicylic acid wherein the salicylic acid constitutes about 0.01% to 20% by weight of the solution and no propellant contained within a fine mist pump spray dispenser and wherein

the solution has a pH above about 5 whereby the likelihood of the fine mist spray causing nasal irritation and coughing is reduced.

20. (Amended) A method for treating acne or acneform conditions on non-facial skin of a [in a ]human comprising administering an effective amount of the fine mist spray of claim 1 to the afflicted skin of said human.

21. (Amended) The spray of claim 1 wherein the sole active anti-acne ingredient(s) in the solution is[consist of] salicylic acid.

22. (Amended) The article of claim 11 wherein the sole active anti-acne ingredient(s) [consist of] in the solution is salicylic acid.